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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,610	12/02/2003	Kenneth A. Martin	1190.10	4996

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EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,610

Applicant(s)

MARTIN ET AL.

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-37 are pending in the application and were examined on their merits.

Election/Restrictions

Applicant's election of 1) bromelain and pepsin, 2) tryptophan, methionine and aspartic acid, 3) seaweeds, algae and grasses (here, the Examiner has interpreted 'grasses' to mean wheat grass and barley grass), 4) Vitamins B, C and E, 5) nutritional grain, 6) whey and soy, 7) saturated fat and 8) seeds and nuts in the reply filed on 8/23/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that Applicant's specific elected combination was not found in the art and therefore another species from each of 1-8 was selected for examination on the merits.

- 1) lipase, papain, lactase, amylase, protease, cellulase and bromelain.
- 2) any naturally-occurring amino acid (the Examiner has found that the vegetables as found in the Tishcon USA supplement will provide for all naturally-occurring amino acids).
- 3) spirulina, chlorella and kelp.
- 4) Vitamins A, B1, B2, B3, B5, B6, B12, C, D and E.
- 5) flax seed meal, apple fiber, oat bran
- 6) soy protein
- 7) saturated fat
- 8) seeds.

Claim Objections

Claim 1 is objected to because of the following informalities:

Claims 1 and 20 recite 'bromelain' twice in the claim rendering the claim redundant.

Claims 9 and 28 recite 'ginger' twice.

Claim 17 recites 'blends of juice'. It appears that this statement should read 'blends of juices'. Further, this claim recites 'and combination thereof' which should properly read 'and combinations thereof'.

Claim 23 recites 'and combination thereof' which should properly read 'and combinations thereof'.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 20 recite 'other non-toxic leafy plants from the sea'. The metes and bounds of this phrase cannot be clearly delineated. Thus, the ordinary artisan would have a difficult time ascertaining exactly what Applicant intends to claim. Clarification is necessary.

Claims 5 and 24 recite 'soy bean derivatives'. This statement is confusing in that a derivative of soybean is not understood. Does Applicant mean varieties of soy beans?

Claim 9 states 'other herbs'. The metes and bounds of this phrase cannot be clearly delineated. Thus, the ordinary artisan would have a difficult time ascertaining exactly what Applicant intends to claim. Clarification is necessary.

Claim 12 states 'complexes thereof'. To what complexes is Applicant referring to? The metes and bounds of this phrase cannot be clearly delineated. Thus, the ordinary artisan would have a difficult time ascertaining exactly what Applicant intends to claim. Clarification is necessary.

Claims 15 and 35 are indefinite because it appears that the claims attempt to broaden, rather than limit claims 1 and 20 respectively via the recitation of 'digestive enzyme'. It is suggested, in order to overcome this rejection, that the claim be reworded to recite' ...of claim 1, wherein the digestive enzyme is present in the composition from about....'.

Although all of the claims were not specifically rejected under this statute, because all of the claims depend either directly or indirectly upon claims 1 or 20, they necessarily provide for all of the limitations of claim 1 and 20 respectively, and are therefore also deemed indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 6, 8-25 and 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lumpur, K (2001).

Lumpur, K (2001) reported that Tishcon USA manufactured a herbal nutritional supplement drink comprising wheat grass, barley green (barley grass), soy protein powder, carrot powder, spirulina, chlorella, red dulse, sea kelp, apple fiber, oat bran, grape seed, flax seed meal, brown rice, calcium, lipase, papain lactase, amylase, protease, cellulase, bromelain, red beet (intrinsically contains beet sugar), ginger and vitamins A, B1, B2, C and E *inter alia* (see p. 2 of Proquest Direct print-out).

It is determined that because the product was a 'drink', it at least contained water, an 'ingestible fluid'. Ingredients such as carrot powder would have imparted a flavor to the composition; thus, it is deemed that carrot powder is a 'flavoring'.

Also, the amino acids as listed in claim 18 would be intrinsic to the proteins found in soy protein powder or any of the herbal or grain ingredients (green tea, brown rice and Gingko for example).

As well known in the art and exemplified by the claims, flax seed is a fiber and inherently contains essential fatty acids from flax seed as recited by the claims.

Lumpur, K. did not specifically teach the amounts of constituents as Instantly claimed.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, it is noted that the claims simply state amounts of constituents, rather than concentrations. The amounts of constituents as present in the claims are rendered somewhat arbitrary because the claims state 'comprising'. Therefore, a substantial amount of carrier may be added to the claims which would render the claimed amounts miniscule. Thus, if there are any differences between Applicant's claimed composition and that suggested by the prior art, the differences would be appear minor in nature.

Additionally, variations of components in nutritional compositions were well known in the art. One of ordinary skill in the art would have been motivated to have modified the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Such variations in amounts of pharmaceutically active ingredients is considered merely optimization of result effective variables, conventional practice in the art of pharmacology.

Claims 7 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lumpur, K (2001) as applied to claims 1- 6, 8-25 and 27-37 above, and further in view of Bell et al. (US 5968896 A).

The teachings of Lumpur, K. (2001) were discussed supra. Lumpur, K. did not teach the incorporation of an artificial sweetener such as aspartame into the composition.

Bell et al. (US 5968896 A) disclosed a nutritional supplement for preoperative feeding which incorporated artificial sweeteners such as aspartame and saccharine (see for example, col. 6, lines 33-39).

Thus, it was clear from Bell et al. that aspartame is routinely added to nutritional supplements. One of ordinary skill in the art would have been motivated to add aspartame to the composition as disclosed by Lumpur, K. in order to impart a sweet flavor to the composition without the addition of added calories in the form of sugar.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized flourish extending from the bottom right.

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11/08/05